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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,325	09/02/2004	Kenji Tayama	1254-0255PUS1	8827

2292 7590 12/20/2007
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EXAMINER	
THOMAS, TIMOTHY P	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
12/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/506,325	TAYAMA ET AL.	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,14 and 16* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The declaration filed on 10/9/2007 under 37 CFR 1.131 is sufficient to overcome the Kondo et al. reference.

Response to Arguments

2. Applicants' arguments, filed 10/9/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

3. Applicant's arguments with respect to the rejection of claim 5 under 35 USC 102(b) filed 10/9/2007 have been fully considered but they are not persuasive:

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Bragg, et al. ("Bragg Apple Cider Vinegar: Miracle Health System"; 1998; cited in previous Office action).

Applicants argue that the Bragg teaching is limited to administration of apple cider vinegar (ACV) for only 48 hours. Applicant argues that the statement made in the previous Office Action that Bragg does not teach a specific consecutive number of days of use in inaccurate, that, in fact, Bragg teaches a 48-hour ingestion regimen, which does not anticipate the 3 week time period requirement amended into the claim. The 4th paragraph of p.38 describes treatment of a woman with high blood pressure that involves two phases: a first phase (48 hour) with 5 ACV doses per day, which was

followed by an unspecified period (a second phase) of "correct eating", the Bragg Healthy Lifestyle, **and ACV** program (a second phase with fewer oral daily doses of ACV, three times daily is described on p. 96, 2nd paragraph). The length of time the woman with high blood pressure was given ACV during the 2nd phase is not specified, except for a general reference to "a short period". Although the case history of the woman along with other teaching passages of Bragg support an obviousness rejection, it is acknowledged that the total length of time the woman was administered ACV has not been specified clearly enough to anticipate the claim.

However, the teaching of Bragg still anticipates the amended claim for the following reason. The subject matter of the claim has been shifted from a method for "preventing, ameliorating, or treating hypertension" to a method for "inhibiting the elevation of blood pressure", without the specification of a required patient population, or the presence of elevated blood pressure in those patients. Any administration of the dose range of the claim with compositions containing the specified concentration of acetic acid for any time period of 3 weeks or longer will anticipate the claim. The 5th paragraph on p. 38, in the section on normalized blood pressure, states, "we have been using the ACV program in the Bragg family for over five generations and it has brought wonderful results for our health". Therefore, the Bragg family members taking ACV daily for five generations (longer than and including the required three week time period) anticipates the claim.

Applicant also argues that Bragg does not teach or suggest an effective threshold dose of 0.5-5.00 g acetic acid. A difference is noted between applicant's

argument of "an effective threshold dose" and the requirement of the claim language, "the total aggregate amount of acetic acid...ingested per day is 0.5 g to 5 g". Bragg does teach the total aggregate amount ingested daily. The ACV program involves ingestion of 1-2 teaspoons ACV (5-10 mL, corresponding to 0.25 - 0.5 g acetic acid), taken three times a day (p. 96, 2nd paragraph), which gives an aggregate amount of 0.75-1.5 g/day, a range that anticipates the total aggregate dose requirement of the instant claim.

Claim Objections

4. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has introduced new matter into the claim. The amount of 25 mg on p. 20, line 2 of the specification is a dosage, not an amount per 1000 g. The 1.25 g of sodium acetate per 100 g listed in the specification corresponds to 0.91 g acetic acid per 100 g (1.25g x MM (acetic acid) / MM (sodium acetate) = 0.91 g) or 9.1 g per 1000

g. This amount does not provide written support for the claim of 25 g per 1000 g. Therefore the newly introduced range is new matter.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mindell ("Amazing Apple Cider Vinegar" 1999; pp. 23-24, 32; cited on PTO-892 form mailed with 4/9/2007 Office Action) or Mindell in view of Bragg (Bragg Apple Cider Vinegar: Miracle Health System; 1998; cited in previous Office action).

Mindell teaches a dose of two tablespoons of vinegar and two tablespoons of honey in a glass of water with breakfast each day is believed to normalize blood pressure while lowering cholesterol (p. 33, Blood Pressure paragraph). Assuming the vinegar contains 5% acetic acid (50 g / 1000 g vinegar), 2 tablespoons (about 30 mL) in a cup (about 237 mL) corresponds to a beverage containing about 6.3 g acetic acid / 1000 g beverage and a daily dose of 1.5 g acetic acid. Mindell does not teach a length of time for continuing the treatment. It would have been obvious to one of ordinary skill in the art at the time of the invention to continue the treatment of Mindell for at least 3 weeks. The motivation to continue treatment is taught by Mindell, to normalize blood pressure. Alternatively, it might be argued that Mindell does not clearly suggest at least three weeks. Bragg teaches his family members have used vinegar daily for over five generations and it has brought wonderful results for their health (p. 38, 5th paragraph). It would have been obvious to one of ordinary skill in the art at the time of the invention

to utilize the method taught by Mindell for a minimum of 3 weeks. The motivation to combine is the promise of normalizing blood pressure, taught by both Bragg and Mindell.

Conclusion

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner

Ardin H Marschel 12/16/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER